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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/445,218	01/28/00	ROSSI C	3687-2

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EXAMINER	
OSWECKI, J	
ART UNIT	**PAPER NUMBER**
1626	6

DATE MAILED: 08/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/445,218	Carla Rossi
Examiner	**Group Art Unit**
Jane Oswecki	1626

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-27* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-17, 19-22, 25, and 26* is/are rejected.

☒ Claim(s) *18, 23, 24, and 27* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-27 are pending in the application.

Claim Rejections - 35 USC § 101

The following quotation from 35 U.S.C. 101 forms the basis for all lack of statutory class rejections found within this Office action:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15 and 16 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter. "Use of" is not a recognized statutory class.

Claim Rejections - 35 USC § 102

The following quotation from 35 U.S.C. 102 forms the basis for all lack of novelty rejections found within this Office action: "A person shall be entitled to a patent unless-

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims 1-15, 17, 19, 21, 22, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by EPO 080,053 to Gruppo Lepetit S.p.A. ("Galliani et al.") and U.S. 4,535,090 to Galliani et al.

The applicant claims optionally substituted diphenyl-1,2,4-triazole derivative compounds which have antigestative, antitumor and immunosuppressant activity.

Galliani et al. disclose optionally substituted 3,5-diphenyl-1H-1,2,4-triazole derivative compounds, compositions comprising and methods of using the compounds as antigestative

agents (EPO 080,053, Abstract; U.S. 4,535,090, Abstract). The compounds disclosed by Galliani et al. are identical to those instantly claimed where the instant substituents have the following meanings: "R" is H or -COR_8 and R_8 is saturated or unsaturated hydrocarbon of C_{1-10}; "R_1" is phenyl substituted by lower alkyl or alkoxy or substituents on phenyl join to form a methylenedioxy group; "R_2" is phenyl-CH_2OR_5 and R_5 is -C(=O)-Z where Z is O-aliphatic chain, the aliphatic chain being saturated or unsaturated (EPO 080,053, Abstract; U.S. 4,535,090, Abstract). Thus, Galliani et al. anticipate the instant claims 1-15, 17, 19, 21, 22, 25 and 26.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17, 19-22, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPO 080,053 to Gruppo Lepetit S.p.A. ("Galliani et al.") and U.S. 4,535,090, to Galliani et al.; FR 2,440,364 to Gruppo Lepetit S.p.A. ("Omodei-Sale et al."), and U.S. 4,888,350 and U.S. 4,459,302, both Omodei-Sale et al.

The applicant claims optionally substituted diphenyl-1,2,4-triazole and optionally substituted diphenyl-imidazole derivative compounds that may have carbonate, carbamate and/or phosphate substituents among other substituent groups. The instant compounds have antitumor, antigestative and immunosuppressant activity.

To any extent that EPO 080,053 and U.S. 4,535,090 may be found not to anticipate the instant claims 1-17, 19-22, 25 and 26, these same claims are rendered obvious by Galliani et al.

Galliani et al. teach optionally substituted 3,5-diphenyl-1H-1,2,4-triazole derivative compounds, compositions comprising and methods of using these compounds as antigestative agents (EPO 080,053, Abstract; U.S. 4,535,090, Abstract). The compounds taught by Galliani et al. are like those instantly claimed where the instant substituents have the following meanings: "R" is H or $-COR_8$ and R_8 is saturated or unsaturated hydrocarbon of C_{1-10}; "R_1" is phenyl substituted by lower alkyl or alkoxy or substituents on phenyl join to form a methylenedioxy group; "R_2" is phenyl-CH_2OR_5 and R_5 is -C(=O)-Z where Z is O-aliphatic chain and where the aliphatic chain is saturated or unsaturated (EPO 080,053, Abstract; page 1, line 12 to page 2, line 2; and page 26, line 1 to page 28, line 30; U.S. 4,535,090, Abstract). Galliani et al. do not teach antigestative compounds that are diphenyl-imidazole derivatives, or diphenyl-imidazole or diphenyl-triazole derivative compounds that have a phosphorus or phosphate substituent.

Omodei-Sale et al. teach contraceptive agents which are optionally substituted acyl-3,5-diphenyl-1H-1,2,4-triazole derivative compounds, compositions comprising and processes for preparing the same (FR 2,440,364 at page 1, line 16 to page 2, line 28; U.S. 4,888,350, Abstract; U.S. 4,459,302, Abstract). The optionally substituted diphenyl-triazole derivative compounds taught by Omodei-Sale et al. are like the compounds of the instant application where the instant substituents "R" and "R_1" are defined similarly to "R", "R_1" and "R_4" of Omodei-Sale et al., and instant substituent "R_2" is defined as comparable to substituents "R_2" and "R_3" of Omodei-Sale et

al., particularly where the Omodei-Sale et al. compounds may have a carbonate or carbamoyl moiety (FR 2,440,364 at page 1, line 16 to page 2, line 28 and page 20, line 1 to page 23, line 21); U.S. 4,888,350, Abstract; U.S. 4,459,302, Abstract). Omodei-Sale et al. differ from the instant application in that they do not teach optionally substituted imidazole derivative compounds nor substituents that are phosphate or carbamate radicals.

It would have been obvious to one skilled in the art at the time the invention was made to have utilized the teachings of Omodei-Sale et al. or Galliani et al., and to have arrived at the optionally substituted diphenyl-1,2,4-triazole derivative compounds of the instant application. A skilled artisan would have been motivated by the prior art teachings in the expectation that compounds of such structural similarity would exhibit similar properties.

Claim Rejections - 35 USC § 112, First Paragraph

The following quotation of 35 U.S.C. 112, first paragraph, forms the basis for all rejections based on lack of enablement found within this Office action:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 1, 19, 20, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some "groups able to form a bond with a nitrogen atom",

"systems suitable for transdermal release", "proper aqueous systems suitable for intravenous administration", "previously disclosed anti-microbic agents" and "previously disclosed anti-oxidative agents", does not reasonably provide enablement for all such groups and systems. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, certain factors must be considered under the holding in In re Wands, 8 U.S.P.Q.2d 1400, 1404 (CAFC, 1988): 1) the nature of the invention is that of anti-gestative, anti-tumor and immunosuppressive agents; 2) the state of the prior art is that such agents are known; 3) with respect to making the instant compounds, the claims include an "R" substituent that is any group able to form a bond with a nitrogen atom; and with respect to using the instant compounds, the claims include suitable systems for transdermal and IV release, in addition to use with previously disclosed anti-microbic and anti-oxidative agents; 4) the level of ordinary skill in the art is high; 5) the level of predictability within the art is low; 6) the inventor provides limited guidance for topical, transdermal and IV injectable materials by suggesting different vegetable oils, but offers no guidance for anti-microbial and anti-oxidative agents; in addition, the instant compounds all appear to have only hydrogen as an "R" substituent; 7) there are working examples but they do not further elucidate the types of suitable systems and "R" substituents that may be employed; 8) thus, an undue quantity of experimentation is needed to make and use the invention based on the content of the disclosure In re Wands 8 USPQ2d 1400, 1404 (CAFC, 1988).

35 U.S.C. 112, Second Paragraph

The following quotation of 35 U.S.C. 112, second paragraph, forms the basis for all lack of clarity rejections found within this Office action:

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 1 and 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague by the phrase, "...or R represents any other group able to form a bond with a nitrogen atom;", since nearly all atoms and myriad groups of atoms fall into this category. Applicant's intent is unclear as to which "R" substituents are appropriate.

The applicant's intent is unclear in claims 19, 20, 23 and 24 as to what is meant by "...systems suitable for a transdermic release"; "...proper aqueous systems..."; "...previously disclosed anti-microbic agents"; and "...previously disclosed anti-oxidative agents", respectively.

Regarding claims 21 and 22, the phrases "i.e...." followed by suggested examples in claim 21, and "such as" in claim 22 render these claims indefinite because it is unclear whether the limitations following each of the phrases are part of the claimed invention. See MPEP § 2173.05(d).

Appropriate correction is required in all instances.

Claim Objections

Claims 1, 2 and 5 are objected to for comprising two sentences, where accepted claim practice requires the presence of a single sentence. See MPEP 608.01(k)-(n).

Claim 14 is objected to under 37 C.F.R. 1.75 as being a substantial duplicate of claim 13. When two claims in an application are duplicates or else so close in content that they cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP 706.03(k).

The following claims are objected to as containing extraneous punctuation: claims 2-4, 6-13, 15-21 and 23-25.

Claims 26 and 27 are objected to for the presence of the word "carbonatante". Correction to an appropriate English equivalent is requested.

Claim 27 is objected to for the presence of the parenthetical term "($COCl_2$)". The use of parentheses implies that additional or explanatory information is contained therein, while claims are to be written in a clear and concise manner. Appropriate correction is required.

In addition, claims 1-5 and 13-16 are objected to for being written in plural rather than singular format, and claims 6-12 and 17-26 for not being in proper idiomatic English so as to reflect acceptable U.S. practice (37 C.F.R. 1.52(a) and (b)).

Claims 18, 23, 24 and 27 are objected to as depending from a rejected base claim.

Specification

Abstract

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Substitute Sheets

The following pages of the specification require substitute sheets because of extraneous lines and markings: pages 6-9, 15, 21, 24, 26, 27, 34, 42-45a, 52 and 53.

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Oswecki whose telephone number is (703)305-7152. The examiner can normally be reached Monday through Thursday from 7:30 AM to 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (703)308-4537. The telephone number for this Group is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-1235.

Jane Oswecki
Patent Examiner
Art Unit 1626

10 August 2000